REMARKS

Claims 1-16 and 20-21 are pending in the instant application. Claims 1-15 and 20 have been rejected and Claim 21 has been withdrawn from consideration by the Examiner. By the above amendments, Claim 3 has been canceled, and Claims 1, 4, 5, 7 and 10 have been amended to more particularly point out and distinctly claim that which Applicant regards as the invention. More specifically, Claim 1 has been amended to include the limitation contained in Claim 3 and Claims 4, 5, 7 and 10 have been amended to depend from Claim 1. Applicant maintains that the above amendments are fully supported by the specification as originally filed and do not raise issues of new matter. After entry of the amendments, Claims 1-2, 4-16, and 20-21 will remain pending and under consideration.

The Examiner has required restriction in the above-referenced application to one of the Groups I or II. Applicant hereby confirms election of the invention of Group I with traverse.

There are two criteria for a proper restriction requirement between patentably distinct inventions: (1) the inventions must independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. MPEP 803. Applicant agrees with the Examiner's findings that the alleged separate inventions are patentable over each other; however, Applicant urges that there is no serious burden on the Examiner in combining the restricted groups into one application. More specifically, since Claim 21 ultimately depends from Claim 1, one the Examiner determines that Claim 1 is patentable, no additional effort is necessary to determine that Claim 21 is also patentable. Therefore,

Applicant respectfully requests that the Examiner withdraw the restriction requirement.

The Examiner has rejected Claims 1-15 and 20 under 35 U.S.C. §103(a) as being unpatentable over Putteman et al. (US 5,814,330) or EP 689844 or WO 94/12217. The Examiner alleges that the components of Applicant's claimed composition "are well-known to be combined in dosage forms which release difficulty soluble active agent" thereby rendering Applicant's invention obvious. Applicant respectfully traverses this rejection.

Putteman et al. disclose compositions comprising a drug (e.g., itraconazole) and cyclodextrin which are emulsions consisting of an aqueous phase and an oil phase (*see e.g.*, column 4, lines 6-7 of Putteman et al.). By contrast, Claim 1, as amended, claims a pharmaceutical composition comprising a sparingly soluble drug, a cyclodextrin, a physiologically tolerable a water-soluble acid, and a physiologically tolerable water-soluble polymer wherein the physical state of the composition is a glass thermoplastic phase. The specification on page 3, lines 13-16 explains the term "glass thermoplastic phase" as meaning that "all components are dispersed so as to form a system that is chemically and physically uniform or homogenous throughout, or consists of one phase as defined in thermodynamics." Applicant submits that the teaching of Putteman et al. of bi-phasic emulsions would not motivate one of ordinary skill in the art to make Applicant's compositions where all the ingredients form a single solid phase. Thus, Applicant urges that Putteman et al. do not render Applicant's claimed invention obvious.

EP 689,844 (hereinafter EP '844) discloses pharmaceutical compositions which are made by mixing a complex of vinpocetine and cyclodextrin (as the active substance) with pharmaceutically acceptable inert carriers and/or additive materials. (See EP '844 on page 17, lines 3-5). Thus, EP '844 describes compositions comprising bi-phasic systems. By contrast, amended Claim 1 is limited to a pharmaceutical composition comprising a sparingly soluble drug, a cyclodextrin, a physiologically tolerable a water-soluble acid, and a physiologically tolerable water-soluble polymer wherein the physical state of the composition is a glass thermoplastic phase. Applicant's specification on page 3, lines 13-16 explains the term "glass thermoplastic phase" as meaning that "all components are dispersed so as to form a system that is chemically and physically uniform or homogenous throughout, or consists of one phase as defined in thermodynamics." Applicant submits that the teaching of EP '844 of a bi-phasic composition would not motivate one of ordinary skill in the art to make Applicant's compositions where all the ingredients form a single solid phase. Thus, Applicant submits that EP '844 does not render Applicant's claimed invention obvious.

WO 94/12217 teaches a pharmaceutical composition comprising a therapeutic agent, a carboxy-containing polymer and cyclodextrin in an aqueous medium (*see, e.g.*, page 17, lines 3-5 of WO 94/12217). By contrast, amended Claim 1 is drawn to a pharmaceutical composition having a physical composition, which is a glass thermoplastic phase. That is, a uniform or homogenous, single, solid phase. Applicant submits that the teaching of WO 94/12217 of a composition in a liquid phase would not motivate one of ordinary skill in the art to

make Applicant's claimed compositions where all the ingredients form a single solid phase. Thus, Applicant submits that EP '844 does not render Applicant's claimed invention obvious.

Since none of the cited references, either individually or in any combination, would motivate one of ordinary skill in the art to make the claimed pharmaceutical compositions wherein the physical state is a glass thermoplastic phase, as is required by amended Claim 1, Applicant maintains that the Examiner has failed to make a *prima facie* case of obviousness. Applicant therefore respectfully requests that the Examiner withdraw the rejection of Claims 1-15 and 20 under §103(a) as being unpatentable over Putteman et al. or EP 689844 or WO 94/12217.

The Examiner has rejected Claim 19 under 35 U.S.C. § 101. Applicant submits that Claim 19 was canceled in the Preliminary Amendment dated December 2, 1999, thereby rendering this rejection moot.

Claims 1-15 and 20 have been rejected by the Examiner under 35 U.S.C. § 112, second paragraph. Applicant does not clearly understand the Examiner's reason for objection of the claims as being vague and/or indefinite; Applicant thus requests that the Examiner specifically point out the grounds for rejection in a subsequent Office Action. However, Applicant maintains that the metes and bounds of amended Claim 1, and all claims depending therefrom, are readily defined such that a potential infringer could readily determine whether conduct was within or outside the scope of the claims. Therefore, Applicant urges that §112, second paragraph is

satisfied, and Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-15 and 20 under § 112, second paragraph.

In view of the above amendments and comments, Applicant maintains that the application is in condition for allowance and passage to issue is earnestly requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned **"Version with Markings to Show Changes Made"**.

Respectfully submitted,

Mary A. Appollina
Attorney for Applicant
Reg. No. 34,087

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3742
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Attachments

Version with Markings to Show Changes

In the Claims:

1. (Amended) A pharmaceutical composition comprising a no more than sparingly water-soluble drug compound, a cyclodextrin, a physiologically tolerable water-soluble acid, and a physiologically tolerable water-soluble organic polymer, wherein the physical state of said composition is a glass thermoplastic phase.

4. (Amended) The composition of claim ~~3~~ 1 wherein the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin.

5. (Amended) The composition of claim ~~3~~ 1 wherein the acid is selected from the group comprising citric, fumaric, tartaric, maleic, malic, succinic, oxalic, malonic, benzoic, mandelic and ascorbic acid.

7. (Amended) The composition of claim ~~3~~ 1 wherein the polymer is selected from the group comprising

- alkylcelluloses such as methylcellulose,
- hydroxyakylcelluloses such as hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and hydroxybutylcellulose,
- hydroxyalkyl alkylcelluloses such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose,
- carboxyalkylcelluloses such as carboxymethylcellulose,
- alkali metal salts of carboxyalkylcelluloses such as sodium carboxymethylcellulose,
- carboxyalkylalkylcelluloses such as carboxymethylethylcellulose,
- carboxyalkylcellulose esters,

- starches,
- pectins such as sodium carboxymethylamylopectin,
- chitin derivates such as chitosan,
- heparin and heparinoids,
- polysaccharides such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, tragacanth, agar-agar, gum arabic, guargum and xanthan gum,
- polyacrylic acids and the salts thereof,
- polymethacrylic acids and the salts thereof, methacrylate copolymers,
- polyvinylalcohol,
- polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate,
- polyalkylene oxides such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide, e.g. poloxamers and poloxamines.

10. (Amended) The composition of claim ~~3~~ 1 wherein the drug is a basic compound.